What Has Covid-19 Exposed in Bioethics? *Four Myths*

by Susan M. Wolf

Already, we are talking about getting back to normal. Vaccination has reached a majority of the U.S. population aged sixty-five and over. According to statistics from the Centers for Disease Control and Prevention, most adults have now received at least one dose. Though SARS-CoV-2 variants are still driving surges, the overall death toll is not rising as rapidly as it was, and the intensive care unit census is easing. For better or worse (and there may be plenty of the latter yet to come), states are relaxing restrictions. The comforting mantra of "build back better" nods to the past year's devastation but looks forward. The increasingly widespread theme of "lessons learned" promises improvement.

Not so fast.

Count your losses first. There's no real learning otherwise. Clear-eyed, no evasion—how did bioethics do? What tenets have failed, what practices have done harm, what presumptions in our field have been proven wrong? What shortcomings and misconceptions has Covid-19 exposed in bioethics?

It's important to ask this now—to learn midstream. The virus is evolving. Experts warn of epidemiological shifts now threatening children. Vaccine access remains a lethal patchwork, in our own states and the world. It is not clear that there will be an end to Covid. Instead, it may become a chronic (though more manageable) threat. And after the parade of SARS, MERS, Ebola, H1N1, Zika, and Covid-19, what pathogen comes next? Like biomedicine, bioethics needs to learn. What has Covid already taught us?

Myth 1: We will know when crisis standards of care apply. Bioethics helped build the three-stage model of response to emergencies: conventional conditions, escalating to contingency conditions when necessary, and then transitioning to crisis conditions if contingency adaptations fail and resource scarcity becomes acute. When the Institute of Medicine advanced this model in 2009 in *Guidance for Establishing Crisis Standards of Care: A Letter Report*, the idea was that an emergency like a global pandemic could get bad enough to make conventional care and even the next stage, functionally equivalent "contingency care," impossible. Faced with extreme scarcity, a state authority (such as the state's commissioner of health) would then declare the activation of crisis standards of care (CSC). "This change in the level of care . . . is formally declared by a state government," the IOM stated (p. 3), reiterating the message in 2012 and again in March 2020 with the Covid-19 pandemic emerging. Activating CSC shifts the ethics of clinical care from the customary focus on the individual patient's preferences and well-being to the community's survival and the saving of the most lives. Only in CSC would triage of ventilators and other scarce critical care resources—choosing one patient over another to receive a life-saving resource—be allowed.

Confronted with an onslaught of Covid-19 patients in long-term care facilities, emergency departments, and ICUs; with patients spilling into field hospitals, gift shops, and chapels; and with the deceased moved into rolling morgues on the street, bioethics has generated an outpouring of guidelines and articles on crisis standards in the pandemic. Who gets the ventilator when all cannot? Who receives scarce medication like remdesivir? Who gets an ICU bed?

But there was a problem. We thought governors, or commissioners of health, or someone in charge would say, "Crisis now!" It would be clear when to start (and later stop) our crisis frameworks. We thought we would see the crisis, marked in bold red letters.

The reality is that, in many places, no one has explicitly declared crisis standards of care. States vary in who has the authority to trigger CSC. Even when conditions were horrific, when patients were stuck in ambulances for hours awaiting admission, sharing ventilators, jammed in hallways, too often neither governments nor hospitals were willing to publicly announce the onset of crisis standards.

So it frequently wasn't clear when the frameworks for crisis ethics kicked in and when they stopped. In mid-December, the National Academy of Medicine with others pled for a shift to CSC as Covid-19 cases climbed. Yet few officials or even hospitals expressly triggered this shift. Governors might have declared a statewide emergency lasting months, with surges coming and going and personal protective equipment (PPE) lacking, then arriving. But within the larger context of a prolonged "emergency," it wasn't clear when a health care facility or region or state was in CSC. Indeed, some resources might have been in acute scarcity, while other resources were not, and some facilities or regions might have been in acute crisis while others were not.

Without clarity on when CSC applied, transparency and accountability were jeopardized. Patients and families

had no sure way to know when CSC were operative. Protections that were designed to limit triage to CSC and then impose safeguards (such as use of triage teams instead of bedside clinicians to decide between patients, antibias training, and retrospective analysis to detect failure to follow guidelines and inequitable impact) failed to kick in reliably.

Myth 2: We will be able to separate questions of clinical, research, and public health ethics. Bioethics has historically held that clinical, research, and public health ethics are distinct. Creative work in zones of overlap—such as translational research bridging research and clinical care—has proven the point that we start from separate spheres. Law, too, has treated the three domains as separate.

The Covid pandemic has blown up those boundaries. When the efficacy of convalescent plasma or monoclonal antibodies is unclear, researchers and clinicians face excruciating questions, including whether to require patients to enroll in a randomized clinical trial (RCT) to have a chance for access to the intervention. The U.S. Food and Drug Administration's emergency use authorization of medications still under study has ignited fierce debate on exactly this question. For the clinician desperate to save their patient and for the family well aware that patients in other facilities are getting the treatment outside of a trial, a facility's insistence on randomization problematically intermixes research and care.

As Derek Angus at the University of Pittsburgh has argued, reconciling the need for research with the clinical imperative to save lives forces debate over issues including the necessity of placebo-controlled RCTs, whether adaptive trial platforms are warranted that adjust treatment arms and the proportions of participants assigned to each arm as knowledge accumulates in a Bayesian process, and whether observational studies contribute useful knowledge. This interdigitation of research and clinical care is further complicated when the intervention under study is scarce, raising the question of whether random allocation should be used to satisfy public health ethics while fueling a clinical trial by creating a randomized sample and adding clinical knowledge.

Is the interdigitation of research, clinical care, and public health merely a creature of the pandemic, a complexity that will recede? It's doubtful. More likely, the pandemic is schooling us that interdigitation is the norm. Bioethics started simple and needs to grow up fast.

Myth 3: We will know when bioethics is succeeding. The Covid pandemic has prompted a rush of bioethics articles, blogs, guidelines, and frameworks. Top journals have published article after article debating allocation by age, comorbidities, quality-adjusted life years, area deprivation index (ADI), and other factors. States have turned to ethics committees to formulate frameworks for allocating treatments and vaccines. I co-lead such a committee (the Minnesota Covid Ethics Collaborative) and can attest to the months of collective effort. In writing an article for *Mayo Clinic Proceedings* on our experience creating a framework for remdesivir allocation, we found a wide range of approaches reported across other states.

Which of these approaches—to allocating treatments, to deciding when clinicians can decline to perform aerosolizing procedures for lack of PPE, to determining priority groups based on essential worker status or ADI—is better? Answering that requires research into how those frameworks are being effectuated and with what impacts on all stakeholders. Otherwise, we have no idea what is working and what is failing. Bioethics cannot stop at journal articles and guidance posted on the websites of our health care systems and departments of public health. That rarified world is far removed from the patients gasping for air, nursing home residents in panicked isolation, and ICU personnel at the end of their rope. Only research can illuminate what actually works. Without those data, we are flying blind.

Myth 4: Bioethics has the means to succeed. There is wide agreement that bioethics needs to do more to include diverse perspectives and address the urgent concerns of Black, Indigenous, and other communities of people of color. But it will take much more than this to render our tools and methods adequate. Abigail Echo-Hawk, who directs the Urban Indian Health Institute, has argued that American Indian and Alaska Native communities hold crucial knowledge. She urges, "Come to us because we have the answers, not because you think we have all the problems." Stephen Thomas, the director of the Maryland Center for Health Equity, has turned to Black barbers and hairstylists as pivotal community leaders with invaluable insight and crucial influence. These are only two examples of approaches that have much to teach our field. Bioethics often applauds community-based participatory research as a strategy for biomedical researchers, without recognizing the inadequacy of our own bioethics methods. This pandemic has been a crash course in the lethal realities of health inequity as well as the failure of bioethics to learn from and genuinely partner with the communities affected.

Customary bioethics approaches will not resolve this pandemic's debates over how to allocate resources in the face of long-standing health disparities and structural disadvantage. Nor will familiar bioethics strategies ensure trusted access to vaccines in communities with a long history of inadequate access to health care and ample grounds for mistrust. Progress on these urgent ethical issues will require new learning from patients and communities.

The path forward in bioethics starts with an honest account. We need to seize this opportunity to abandon misconceptions and outmoded strategies. The Covid pandemic should open our eyes. Bioethics must rise to the challenge.

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